REMARKS

The Claims

The Examiner has withdrawn Claims 69 and 70 from further consideration as being drawn to a non-elected species. Applicant hereby cancels Claims 69 and 70 but reserve the right to introduce said claims for further consideration upon the allowance of a generic or linking claim. Claims 58-68 are currently pending in the application.

Submission of New Drawings

In response to the request by the Examiner, Applicant submits herewith a replacement set of drawings for the present application. In order to improve the quality of the data being presented in figures 2A-2C, 3, 7A-7C, 9A-9D, 11A-11C, and 12A-12G, black and white photographs are being submitted for these figures as photographs are the only practicable medium for illustrating the claimed invention.

Abstract of the Invention

The Examiner has objected to the abstract as it allegedly does not disclose the claimed invention (the method of Claim 58). Upon an indication of allowable subject matter, Applicant will amend the abstract accordingly.

Rejections under 35 U.S.C. 112

Claims 58-62 and 64-68 are rejected under 35 U.S.C. 112, first paragraph, as the specification allegedly does not provide adequate written description of the claimed invention. The Examiner argues that there is no support in the specification as originally filed for the claimed methods. It is argued that the claims encompass use of in vivo assays and unspecified assays whereas original Claim 43 and the specification at p. 23 only recite an in vitro method wherein OPGbp/ligand binding is measured. The Examiner further argues that there is no description as to how to measure agonist or antagonist activity.

Applicant traverses the rejection. Claim 58 and claims depending therefrom are fully supported by the specification and that no new matter has been introduced. The specification

discloses the use of both in vitro and in vivo assays to determine the interaction of OPGbp with ODAR and to measure OPGbp activity. In addition to the description of in vitro assays for osteoclast formation starting on p. 29, line 22 of the specification, a description of in vivo assays is found at p. 30, lines 8-15. Moreover, Example 15 starting on p. 66 describes in detail the use of an in vivo assay with one compound, an ODAR-Fc fusion protein, to demonstrate the inhibition of OPGbp activity in normal mice. Contrary to the Examiner's assertion, this method allows one to determine antagonist activity of the compound. The claimed methods are fully supported for both in vitro and in vivo assays.

The Examiner argues that original Claim 43 recites only an in vitro method. Applicant is not relying solely on the claims for written description and one may rely on the specification for drafting claims regardless of the scope and wording of previously presented claims. It should also be noted that original Claim 29 in U.S. Serial No. 09/052, 521 claimed a method of detecting binding of a compound to OPbp which was not limited to in vitro methods.

The Examiner has failed to establish a lack of written description for the claimed methods and Applicant requests that the rejection be withdrawn.

Claim 60 is rejected under 35 U.S.C. 112, first paragraph, as the specification allegedly does not provide adequate written description of the claimed invention. The specification discloses murine ODAR in Figure 10 whereas the claimed method encompasses the use of any mammalian ODAR, including human ODAR and ODAR variants, mutants and alleles. The Examiner argues that the specification lacks sufficient written description for ODAR proteins that are encompassed by the claims.

Without acquiescing to the rejection and solely to advance prosecution, Applicant has amended Claim 60 to recite human ODAR. Support for the amendment is found at p. 26, lines 15-20 of the specification which references the previously published amino acid sequence of human RANK, the human homolog of murine ODAR.

Claims 58, 60 and 62-68 are rejected under 35 U.S.C. 112, first paragraph, as the specification allegedly does not provide adequate written description of the claimed invention. The Examiner argues that the preamble of Claim 58 recites OPGbp of SEQ ID NO: 4 whereas the method steps of Claim 58 allegedly encompass use of OPGbp other than that recited in the preamble. Thus, the Examiner argues that the claims encompass use of any mammalian OPGbp, including OPGbp variants, mutants

and alleles but the specification lacks sufficient written description for OPG binding proteins that are encompassed by the claims.

Without acquiescing to the rejection and solely to advance prosecution, Applicant has amended Claim 58 to recite "OPGbp of Figure 4 (SEQ ID NO: 4), or a soluble form thereof". Support for the amendment is found in Claim 59. Claim 59 has been amended to recite the compound which binds to OPGbp of Figure 4 (SEQ ID NO: 4). It is believed that the rejection may be withdrawn.

Rejection under 35 U.S.C. 103

Claims 58-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle (U.S. Patent No. 6,316,408) in view of Choi et al. (WO 02/16551).

Applicant traverses the rejection. U.S. Patent 6,316,408 to Boyle (hereafter "the '408 patent") and the present application both claim priority back to U.S. Serial No. 08/842,842 filed April 16, 1997. Choi et al. claims priority to August 18, 2000 or more than three years after the priority date of the present application. The Examiner argues that the '408 patent and Choi et al. may be properly cited as the claims of the present application are not allegedly not entitled to their priority dates in view of the rejections under 35 U.S.C. 112. As explained above, no new matter has been introduced into Claims 58-68 and therefore the '408 patent and Choi et al. are not prior art to the present application and cannot form the basis for a rejection under 35 U.S.C. 103. The rejection is moot and should be withdrawn.

CONCLUSION

It is believe that Claims 58-68 are in condition for allowance and an early notice thereof is solicited.

Respectfully submitted,

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